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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
COLLINS, CYNTHIA E	

ART UNIT	PAPER NUMBER
1638	

DATE MAILED: 03/24/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/719,002	DRAPER ET AL.	
	Examiner	Art Unit	
	Cynthia Collins	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 December 2003*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *14-23 and 25-39* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *14-23 and 25-39* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The Amendment filed December 15, 2003 has been entered.

Claims 1-13 and 24 are cancelled.

Claims 14-19, 21-23, 25 and 27 are currently amended.

Claims 29-39 are newly added.

Claims 14-23 and 25-39 are pending.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

All previous objections and rejections not set forth below have been withdrawn.

Claim Rejections - 35 USC § 112

Claims 14-23 remain rejected, and claims 25-39 are rejected, under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, for the reasons of record set forth in the office action mailed August 13, 2003.

Applicant's arguments filed December 15, 2003 have been fully considered but they are not persuasive.

Applicants argue that the rejection should be withdrawn in light of the cancellation of claims 1-14 and the addition of claim 29, which incorporates in part (i) the limitation of cancelled claim 4 which was not rejected for lack of written description. Applicants also argue

that the recitation of SEQ ID NO:1 in the claims provides adequate structure for what is claimed, and Applicants further point to the presence of functional language in the claims that is associated with the core structure of the claimed molecules. Applicants additionally argue that the three species described (the 475 bp AoPRT-L promoter of SEQ ID NO:1, the AoPRT-L promoter salicyclic acid responsive element from -247 to -133 of SEQ ID NO:1, and two copies of the salicyclic acid responsive element placed in front of a -247 bp AoPRT-L promoter) constitute a representative number of species adequate to support the description of the claimed genus (reply pages 9-11).

The rejection is maintained because the claimed genus of promoter sequences is not adequately described. The claims as amended are drawn to a genus of recombinant DNA molecules comprising a promoter that is induced by salicylic acid and benzo (1,2,3) thiadiazole-7-carbothoic acid S methyl ester, not systemically activated by pathogen infection, and exhibiting minimal developmentally-regulated expression, said genus including a nucleic acid molecule having SEQ ID NO:1, a nucleic acid molecule 90% or 95% identical to SEQ ID NO:1, a nucleic acid molecule that hybridizes under unspecified stringency conditions to SEQ ID NO:1 or a sequence 90% identical to SEQ ID NO:1, and a fragment of at least 100 nucleotides of SEQ ID NO:1. However, the specification does not describe the structural features of SEQ ID NO:1 retained by nucleic acid molecules that are 90% or 95% identical to SEQ ID NO:1 and that retain the functional properties of SEQ ID NO:1. The specification also does not describe the structural features of SEQ ID NO:1 retained by nucleic acid molecules that hybridize to SEQ ID NO:1 or a sequence 90% identical to SEQ ID NO:1 and that retain the functional properties of SEQ ID NO:1. The specification additionally does not describe the structural features of SEQ ID

NO:1 retained by a 100 base pair fragment of SEQ ID NO:1 that retains the functional properties of SEQ ID NO:1. Furthermore, the three species described (the 475 bp AoPRT-L promoter of SEQ ID NO:1, the AoPRT-L promoter salicyclic acid responsive element from -247 to -133 of SEQ ID NO:1, and two copies of the salicyclic acid responsive element placed in front of a -247 bp AoPRT-L promoter) do not constitute a representative number of species adequate to support the description of the claimed genus, because each species is 100% identical to SEQ ID NO:1 or a specific portion thereof. Accordingly, the recitation of SEQ ID NO:1 and its functional properties in the claims does adequately describe the claimed promoter sequences, because Applicants have not described a representative number of species falling within the scope of the claimed genus, nor the structural features unique to the genus.

Claims 14-23 remain rejected, and claims 25-39 are rejected, under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a salicylic acid and BTH inducible AoPRT-L promoter of SEQ ID NO:1 obtained from *Asparagus officinalis*, a salicylic acid and BTH inducible promoter element region corresponding to from -247 to -133 of the AoPRT-L promoter of SEQ ID NO:1, and a promoter construct comprising the AoPRT-L promoter of SEQ ID NO:1 operably linked to a synthetic sequence encoding a LhG4 transactivator and a pOP transactivator target promoter sequence, does not reasonably provide enablement for other nonexemplified promoter sequence variants. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims, for the reasons of record set forth in the office action mailed August 13, 2003.

Applicant's arguments filed December 15, 2003 have been fully considered but they are not persuasive.

Applicants argue that the rejection should be withdrawn in light of the cancellation of claims 1-13 and the incorporation into the newly added claims of limitations that are directed to enabled embodiments. Applicants also argue that the specification provides sufficient guidance for one skilled in the art to practice the claimed invention at the time of filing without undue experimentation, such as guidance for the use of probes under stringent conditions to identify the desired promoter sequences and the disclosure of sequences important for inducibility. Applicants additionally argue that only a low amount of experimentation would be required to obtain additional embodiments because multiple species could be easily screened using appropriate probes, and because the specification provides guidance for determining whether a species exhibits the desired promoter activity (reply pages 11-14).

The rejection is maintained because the specification does not provide sufficient guidance for one skilled in the art to make and use the claimed promoter variants without undue experimentation. The claims as amended are drawn to recombinant DNA molecules comprising a promoter that is induced by salicylic acid and benzo (1,2,3) thiadiazole-7-carbothoic acid S methyl ester, not systemically activated by pathogen infection, and exhibiting minimal developmentally-regulated expression, including a nucleic acid molecule having SEQ ID NO:1, a nucleic acid molecule 90% or 95% identical to SEQ ID NO:1, a nucleic acid molecule that hybridizes under unspecified stringency conditions to SEQ ID NO:1 or a sequence 90% identical to SEQ ID NO:1, and a fragment of at least 100 nucleotides of SEQ ID NO:1. However, the specification does not provide guidance with respect to which nucleic acid molecules that are

90% or 95% identical to SEQ ID NO:1 would retain the functional properties of SEQ ID NO:1 and which would not. The specification also does not provide guidance with respect to which nucleic acid molecules that hybridize to SEQ ID NO:1 or a sequence 90% identical to SEQ ID NO:1 would retain the functional properties of SEQ ID NO:1 and which would not. The specification additionally does not provide guidance with respect to which 100 base pair fragments of SEQ ID NO:1 would retain the functional properties of SEQ ID NO:1 and which would not.

Guidance for making and using the claimed promoter variants is necessary because it is unpredictable whether nucleic acid molecules that are 90% or 95% identical to SEQ ID NO:1, that hybridize under unspecified stringency conditions to SEQ ID NO:1 or a sequence 90% identical to SEQ ID NO:1, or that comprise any fragment of at least 100 nucleotides of SEQ ID NO:1 will retain any or all of the specifically recited functional properties of SEQ ID NO:1, because it is unpredictable whether the claimed promoter variants would retain all the particular nucleotide motifs of SEQ ID NO:1 that mediate the specifically recited functional properties.

Guidance for making and using the claimed promoter variants is also necessary because it is unpredictable whether the mere presence of the salicylic acid responsive element of the AoPRT-L promoter alone would be sufficient to confer on variant sequences all of the functional properties of SEQ ID NO:1, as the ability of a promoter element to specifically affect promoter function is context dependent, and the presence or absence of elements other than the salicylic acid responsive element may be required to mediate other specific aspects of promoter function, such as basal promoter function, insensitivity to systemic activation by pathogen infection, and minimal developmental regulation. It is additionally noted that rejected claims 23, 29-30, 33-34

and 36-39 do not require the presence of the salicylic acid responsive element of the AoPRT-L promoter in variant promoter sequences.

Absent guidance with respect to which of the 475 nucleotides of SEQ ID NO:1 would be retained by variant promoter sequences that retain the functional properties of SEQ ID NO:1, it would require undue experimentation to determine which variant sequences would function as claimed and which would not, as every variant sequence would have to be made and tested not only for structural characteristics such as percent identity to SEQ ID NO:1, the ability to hybridize to SEQ ID NO:1 or the presence of the salicylic acid responsive element of SEQ ID NO:1, but also for its inducibility by salicylic acid and benzo (1,2,3) thiadiazole-7-carbothoic acid S methyl ester, whether it is systemically activated by pathogen infection, and whether it exhibits developmentally-regulated expression throughout the life cycle of a plant transformed therewith.

Claims 31 and 35 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 31 and 35 are indefinite in their reference to "from -247 bp to -137 bp of SEQ ID NO:1", because the bases of SEQ ID NO:1 are designated by positive integers only.

Claim 32 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 32 is indefinite because it depends upon itself.

Claim 39 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 39 is indefinite because it depends from cancelled claims 9 and 10.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Remarks

No claim is allowed.

Claims 14-23 and 25-39 are deemed free of the prior art, due to the failure of the prior art to teach or suggest a salicylic acid and BTH inducible AoPRT-L promoter of SEQ ID NO:1

obtained from *Asparagus officinalis*, or the claimed salicylic acid responsive element obtained therefrom, or promoters comprising multiple copies thereof.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cynthia Collins whose telephone number is (571) 272-0794. The examiner can normally be reached on Monday-Friday 8:45 AM -5:15 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on (571) 272-0804. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

CC

DAVID T. FOX
PRIMARY EXAMINER
GROUP ~~180~~ 1638